CHAPTER 50

MODEL ANIMAL HEALTH CERTIFICATE FOR THE ENTRY INTO THE UNION OF CONSIGNMENTS OF OOCYTES AND EMBRYOS OF OVINE AND CAPRINE ANIMALS COLLECTED OR PRODUCED, PROCESSED AND STORED IN ACCORDANCE WITH REGULATION (EU) 2016/429 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AND COMMISSION DELEGATED REGULATION (EU) 2020/692 AFTER 20 APRIL 2021, DISPATCHED BY THE EMBRYO COLLECTION OR PRODUCTION TEAM BY WHICH THE OOCYTES OR EMBRYOS WERE COLLECTED OR PRODUCED(MODEL "OV/CAP-OOCYTES-EMB-A-ENTRY")

CO	DUNTRY			Animal Health Certificate to the EU			
	I.1	Consignor/Exporter Name		I.2	Certificate Reference	I.2a IMSOC Reference	
		Address		I.3 Central Competent Authority			
		Country	ISO country code		Local Competent Authority	QR CODE	
: Description of Consignment	I.5	Consignee/Importer Name Address		I.6	Operator Responsible for the Consignment Name		
					Address		
		Country	ISO country code		Country ISO country code		
	I.7	Country of Origin	ISO country code	1.9	Country of Destinat	ISO country code	
	I.8	Region of Origin	Code	I.10	Region of Destination	n Code	
	I.11	Place of Dispatch Name Registration/Approval Number Address		I.12	Place of Destination Name	Registration/Approval Number	
				Address			
Descripti		Country ISC	country code		Country	ISO country code	
Part I:	I.13	Place of Loading		I.14	Date and Time of De	parture	
	I.15	Means of Transport		I.16	Entry Border Cont	rol Post	
		☐ Aircraft ☐ Vesse	·l				
		□ Railway □ Road	vehicle	I.17			
		Identification					
	I.18	Transport Conditions	☐ Ambient	□ Ch	illed	☐ Frozen	
	1,10	Transport Conditions	□ Amultit	⊔ Cn	iiicu		

I.19	Cont	Container Number/Seal Number Container Num			Jumber Seal Number			
I.20	Certi	Certified As or For						
I.21	□ For	r Transit		I.22 ☐ For Internal Market				
	Third	country ISO country		I.23				
I.24	Total	Number of Packages	1.25	Total Quanti	ity	I.26		
I.27		ription of Consignment						
CN c	ode	Species		Subspeci	ies/Category	Identification number	Quantity	
Type		Approval or registration number of plant/establishment/centre		Identification mark		Date of collection/production	Test	

		Certificate Model OV/C	AI -U	JC I IES-ENID-A-ENIKI
II. Health Information	II.a	Certificate Reference	II.b	IMSOC Reference

I, the undersigned official veterinarian, hereby certify that:

- The [oocytes] (1) [in vivo derived embryos] (1) [in vitro produced embryos] (1) [micromanipulated embryos] (1) described in Part I are intended for artificial reproduction and were obtained from donor animals which originate from a third country or territory, or zone thereof:
 - II.1.1. authorised for the entry into the Union of [oocytes](1) [embryos] (1) of [ovine] (1) [caprine] (1) animals and listed in Annex X to Commission Implementing Regulation (EU) 2021/404;
- (1) *either*[II.1.2. where foot and mouth disease was not reported for at least 24 months immediately prior to the date of
- (1) or [II.1.2. dd/mm/yyyy) immediately prior to the date of collection of the [oocytes] (1) [embryos] (1) and until the date of their dispatch;]
 - where infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des II.1.3. petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia were not reported for at least 12 months immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1) and until the date of their dispatch;
 - II.1.4. where no vaccination against infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia has been carried out for at least 12 months immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1) and until the date of their dispatch, and no vaccinated animals entered into the third country or territory, or zone thereof during that period, and:
 - (1) either Ino vaccination against foot and mouth disease has been carried out for the same period and no vaccinated animals entered into the third country or territory, or zone thereof during that period;]
 - (1) or [vaccination against foot and mouth disease has been carried out for the same period, or vaccinated animals entered into the third country or territory, or zone thereof during that period.
- (1) [II.2. The [oocytes] (1) [in vivo derived embryos] (1) described in Part I have been collected, processed and stored, and dispatched by the embryo collection team (3) which:
 - II.2.1. is approved and listed by the competent authority of the third country or territory;
 - II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Part 2 of Annex I to Commission Delegated Regulation (EU) 2020/686.]
- (1) [II.2. The [oocytes] (1) [in vitro produced embryos] (1) [micromanipulated embryos] (1) described in Part I have been collected or produced, processed and stored, and dispatched by the embryo production team (3) which:
 - is approved and listed by the competent authority of the third country or territory; II.2.1.
 - II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Parts 2 and 3 of Annex I to Delegated Regulation (EU) 2020/686.]
- The [oocytes] (1) [embryos] (1) described in Part I were obtained from donor animals which originate from II.3. establishments:
 - II.3.1. free from infection with Brucella abortus, B. melitensis and B. suis and they have never been kept previously in any establishment of a lower health status.
- (1)(4)in which infection with Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis) [II.3.2. has not been reported during the last 42 days;]
- (1)(5) which is subjected to surveillance to detect infection with Mycobacterium tuberculosis complex (M. [II.3.2. bovis, M. caprae and M. tuberculosis) in caprine animals kept therein in accordance with procedures provided for in Part 1, points (1) and (2), of Annex II to Commission Delegated Regulation (EU) 2020/688 during at least 12 months and during that period:
 - only caprine animals from establishments applying such surveillance have been introduced (i) therein;
 - (1) either [(ii) infection with Mycobacterium tuberculosis complex (M. boyis, M. caprae and M. tuberculosis) has not been reported in the animals of the same species kept therein.]]
 - $^{(1)}or$ infection with Mycobacterium tuberculosis complex (M. bovis, M. caprae and M. tuberculosis) has been reported in caprine animals kept therein and the measures were taken in accordance with Part 1, point 3, of Annex II to Delegated Regulation (EU) 2020/688.]]
 - in which: II.3.3.
 - (1) either [surra (Trypanosoma evansi) has not been reported in the establishments during the last 2 years.]
 - [surra (Trypanosoma evansi) has not been reported during the last 30 days and when the disease was reported in the establishments during the last 2 years, following the date of the last outbreak the establishments have remained under movement restrictions until the date on which the infected animals have been removed from the establishments, and the remaining animals in the establishments have been

subjected to a test for surra with one of the diagnostic methods provided for in Part 3 of Annex I to Commission Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken at least 6 months after the date on which the infected animals have been removed from the establishments.]

- II.4. The [oocytes] (1) [embryos] (1) described in Part I were obtained from donor animals which:
 - II.4.1. were not vaccinated against infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia;
 - II.4.2. remained for at least 6 months immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1) in a third country or territory, or zone thereof referred to in box I.7;
 - II.4.3. for at least 30 days immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1) and during the [collection] (1) [production] (1) period:
 - II.4.3.1. were kept in establishments not situated in a restricted zone established due to the occurrence of foot and mouth disease, infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox or contagious caprine pleuropneumonia, or of an emerging disease relevant for ovine and caprine animals;
 - II.4.3.2. were kept in a single establishment where infection with *Brucella abortus*, *B. melitensis* and *B. suis*, infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), rabies, anthrax, surra (*Trypanosoma evansi*), infection with epizootic haemorrhagic disease virus, infection with bluetongue virus (serotypes 1-24) and, in case of ovine animals and those caprine animals which are kept together with ovine animals, ovine epididymitis (*Brucella ovis*) have not been reported;
 - II.4.3.3. were not in contact with animals from establishments situated in a restricted zone due to the occurrence of diseases referred to in point II.4.3.1 or from establishments which do not meet the conditions referred to in point II.4.3.2;
 - II.4.3.4. were not used for natural breeding;
 - II.4.4. were examined by the team veterinarian or a team member and did not show symptoms or clinical signs of transmissible animal diseases on the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1);
 - II.4.5. are individually identified as provided for in Article 21(1) of Delegated Regulation (EU) 2020/692;
 - II.4.6. comply with the following conditions as regards foot and mouth disease:
 - II.4.6.1. they come from establishments:
 - situated in an area where foot and mouth disease has not been reported within a 10-km radius centred on the establishments for at least 30 days immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1);
 - in which foot and mouth disease has not been reported during at least 3 months immediately prior to the date of [collection] (1) [production] (1) of the [oocytes] (1) [embryos] (1);
 - (1) either [II.4.6.2. they were not vaccinated against foot and mouth disease;]
 - (1)(6) or [II.4.6.2. they were vaccinated against foot and mouth disease during 12 months immediately prior to the date of collection of the embryos and
 - II.4.6.2.1. have not been vaccinated against foot and mouth disease within at least 30 days immediately prior to the date of collection of the embryos;
 - II.4.6.2.2. the semen used for fertilisation was collected from a male donor that complies with the conditions set out in Part 5, Chapter I, point 1(b), of Annex II to Delegated Regulation (EU) 2020/686 or the semen complies with the conditions set out in Part 5, Chapter I, point 2, of Annex II to Delegated Regulation (EU) 2020/686;
 - II.4.6.2.3. prior to freezing, the embryos have been subjected to trypsin washing carried out in accordance with the recommendations of the IETS Manual ⁽⁷⁾;
 - II.4.6.2.4. the embryos were stored deep frozen for at least 30 days from the date of collection, and during this period the donor animal has not shown clinical signs of foot and mouth disease;]
 - II.4.7. comply with at least one of the following conditions as regards infection with bluetongue virus (serotypes 1-24):
 - (1) either [II.4.7.1. they have been kept for at least 60 days immediately prior to the date of and during collection of the [oocytes] (1) [embryos] (1) in a third country or territory, or zone thereof free from infection with bluetongue virus (serotypes 1-24) where no case of infection with bluetongue virus

- (serotypes 1-24) has been confirmed in the targeted animal population during the last 24 months;]
- (1)(14) or [II.4.7.2. they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for at least 60 days immediately prior to the date of and during collection of the [oocytes] (1) [embryos] (1);]
- (1) and/or [II.4.7.3. they have been kept in a vector-protected establishment for at least 60 days immediately prior to the date of and during collection of the [oocytes] (1) [embryos] (1)]
- (1) and/or [II.4.7.4. they have been subjected to a serological test able to detect specific antibodies against all serotypes (1-24) of bluetongue virus, with negative results, between 28 and 60 days from the date of each collection of the [oocytes] (1) [embryos] (1);]
- (1) and/or [II.4.7.5. they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood sample taken on the date of collection of the [oocytes] (1) [embryos] (1);]
- II.4.8. comply with at least one of the following conditions as regards infection with epizootic haemorrhagic disease virus (EHDV):
- (1) either [II.4.8.1. they have been kept for at least 60 days prior to the date of and during collection of the [oocytes]
 (1) [embryos] (1) in a third country or territory, or zone thereof where EHDV has not been reported within a radius of 150 km of the establishment for at least the preceding 2 years;]
- (1)(15) or [II.4.8.2. they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for at least 60 days prior to the date of and during collection of the [oocytes] (1) [embryos] (1);]
- (1) and/or [II.4.8.3. they have been kept in a vector-protected establishment for at least 60 days prior to the date of and during collection of the [oocytes] (1) [embryos] (1);]
- - (1) either [II.4.8.4.1. a serological test able to detect specific antibodies against those serotypes of EHDV, with negative results, on blood sample taken between 28 and 60 days from the date of the collection of the [oocytes] (1) [embryos] (1);]]
 - (1) and/or [II.4.8.4.2. an agent identification test for EHDV, with negative results, on blood sample taken on the date of collection of the [oocytes] (1) [embryos] (1).]]
- (8) [II.4.9. comply with the following conditions as regards classical scrapie:
 - II.4.9.1. have been kept continuously since birth in a third country or territory where the following conditions are fulfilled:
 - II.4.9.1.1. classical scrapie is compulsorily notifiable;
 - II.4.9.1.2. an awareness, surveillance and monitoring system is in place;
 - II.4.9.1.3. ovine and caprine animals affected with classical scrapie are killed and completely destroyed;
 - II.4.9.1.4. the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, has been banned and effectively enforced in the whole country for at least 7 years;
- have been kept continuously for the last 3 years preceding the date of the collection of the embryos to be dispatch to the Union in a holding or holdings which has/have fulfilled during that period all the requirements set out in Chapter A, Section A, points 1.3.(a) to (f), of Annex VIII to Regulation (EC) No 999/2001, except during the period when they were kept at a semen collection centre that complied during that period with the conditions set out in in Chapter A, Section A, point 1.3.(c)(iv), of Annex VIII to that Regulation;]
- (1) or [II.4.9.2. they are ovine animals and the embryos
 - (1) either [are of the ARR/ARR prion protein genotype;]
 - (1) or [carry at least one ARR allele.]]]
- II.5. The [oocytes] (1) [embryos] (1) described in Part I
 - II.5.1. have been collected, processed and stored in accordance with animal health requirements set out in [Part 2] (1) [Part 3] (1) [Part 4] (1) [Part 5] (1) and Part 6 of Annex III to Delegated Regulation (EU) 2020/686;
 - II.5.2. are placed in straws or other packages on which the mark is applied in accordance with requirements provided for in Article 83, point (a), of Delegated Regulation (EU) 2020/692 and that mark is indicated in box I.27;
 - II.5.3. are transported in a container which:

- II.5.3.1. was sealed and numbered prior to the date of dispatch by the embryo collection or production team under responsibility of the team veterinarian, or by an official veterinarian, and the seal bears the number as indicated in box I.19;
- II.5.3.2. has been cleaned and either disinfected or sterilised before use, or is single-use container; has been filled in with a cryogenic agent which has not been previously used for other products;
- (1) (10) [II.5.4. are placed in straws or other packages which are securely and hermetically sealed;
 - II.5.5. are transported in a container where the different types are separated from each other by physical compartments or by being placed in secondary protective bags.]
- (1)(11)[II.6. The [in vivo derived embryos] (1) [in vitro produced embryos] (1) [micromanipulated embryos] (1) described in Part I were conceived by artificial insemination using semen coming from a semen collection centre, germinal product processing establishment or germinal product storage centre approved for the collection, processing or storage of semen by the competent authority of a third country or territory, or zone thereof listed in Annex X to Implementing Regulation (EU) 2021/404 for semen of ovine and caprine animals or by the competent authority of a Member State, and were collected, processed and stored in accordance with the requirements of Part 3, Chapter I and Part 5, Chapters II and III, of Annex II, and Part 1 of Annex III to Delegated Regulation (EU) 2020/686.]
- (1)(12) [II.7. The following antibiotic or mixture of antibiotics (13) has been added to the collection, processing, washing or storage media:

Notes

This animal health certificate is intended for the entry into the Union of oocytes and embryos of ovine and caprine animals, including when the Union is not the final destination of the oocytes and embryos.

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to the Union in this animal health certificate include the United Kingdom in respect of Northern Ireland.

This animal health certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

Part I:

- Box reference I.11: "Place of dispatch": Indicate the unique approval number and the name and address of the embryo collection or production team of dispatch of the consignment of oocytes or embryos. Only embryo
 - collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:
 - http://ec.europa.eu/food/animal/semen ova/ovine/index en.htm.
- Box reference I.12: "Place of destination": Indicate the address and unique registration or approval number of the establishment of destination of the consignment of oocytes or embryos.
- Box reference I.19: Seal number shall be indicated.
- Box reference I.24: Total number of packages shall correspond to the number of containers.
- Box reference I.27: "Type": Specify if *in vivo* derived embryos, *in vivo* derived oocytes, *in vitro* produced embryos or micromanipulated embryos.
 - "Species": Select amongst "Ovis aries" or "Capra hircus" as appropriate.
 - "Identification number": Indicate the identification number of each donor animal.
 - "Identification mark": Indicate the mark on the straw or other packages where oocytes or embryos of the consignment are placed.
 - "Date of collection/production": Indicate the date on which oocytes or embryos of the consignment were collected or produced.
 - "Approval or registration number of plant/establishment/centre": Indicate the unique approval number of the embryo collection or production team by which oocytes or embryos of the consignment were collected or produced.
 - "Quantity": Indicate the number of straws or other packages with the same mark.
 - "Test": Indicate for BTV-test: point II.4.7.4 and/or point II.4.7.5, and/or for EHD-test: point II.4.8.4.1 and/or point II.4.8.4.2, if relevant.

Part II:

- (1) Delete if not applicable.
- Only for a third country or territory, or zone thereof with an opening date in accordance with column 9 of the table in Part 1 of Annex II to Implementing Regulation (EU) 2021/404.
- Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:
 - http://ec.europa.eu/food/animal/semen ova/ovine/index en.htm.
- (4) Applicable for ovine animals.
- (5) Applicable for caprine animals.

COUNTRY

Certificate Model OV/CAP-OOCYTES-EMB-A-ENTRY

- Option available only for the consignment of *in vivo* derived embryos.
- Manual of the International Embryo Technology Society A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Technology Society, 1 111 North Dunlap Avenue, Savoy, Illinois 61 874, USA (http://www.iets.org/).
- Delete if the Union is not the final destination of the oocytes and embryos.
- (9) Applicable for frozen oocytes or embryos.
- (10) Applicable for consignments where oocytes, *in vivo* derived embryos, *in vitro* produced embryos and micromanipulated embryos of ovine or caprine animals are placed and transported in one container.
- Does not apply to oocytes.
- (12) Mandatory attestation in case antibiotics were added.
- (13) Insert the name(s) of the antibiotic(s) added and its (their) concentration.
- For the zones with an entry "SF-BTV" in column 7 of the table in Part 1 of Annex II to Implementing Regulation (EU) 2021/404.
- For the zones with an entry "SF-EHD" in column 7 of the table in Part 1 of Annex II to Implementing Regulation (EU) 2021/404.

2021/404.				
Official Veterinarian				
Name (in capital letters)	Qualification and Title			
,				
Date	Signature			
Date	Signature			
Stamp				
Stamp				